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09/981,927	10/17/2001	Alan Chervitz	MED-8 CIP	6361
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Pandiscio & Pandiscio 470 Totten Pond Road Waltham, MA 02451-1914				
EXAMINER PHILOGENE, PEDRO				
ART UNIT		PAPER NUMBER		
3732				
DATE MAILED: 10/22/2003				

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,927

Applicant(s)

CHERVITZ ET AL.

Examiner

Pedro Philogene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-23,33,34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, line 11, the term "said second axis" lacks prior antecedent basis.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 35 is rejected under 35 U.S.C. 101 because it is drawn to a non-statutory subject matter. In claim 35 line 2, applicant positively part of a human, i.e. "said object is bone". Thus, claim 35 includes a human part within its scope and is non-statutory.

A claim directed to on including within its scope a human part is not considered to be patentable subject matter under 35 U. S. C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the constitution. In re Wakefield, 422 F. 2d 897, 164 USPQ 636 (CCPA 1970).

Allowable Subject Matter

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The indicated allowability of claim 29 is withdrawn in view of the newly discovered reference(s) to Cole et al./Corsi et al.. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7,9,12-19,23-28,31-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Cole et al (6,068,648).

With respect to claims 1, 2,12, Cole et al disclose a structure (32) having a screw hole (321) extending therethrough for receiving therein the shank of the bone screw (79) deployed in the bone, whereby to secure the structure to the bone, the screw hole defining a first axis, as best seen in Fig.9, and the structure having a filament hole (323) extending therethrough for receiving a filament (20) therein so as to retain the filament to the structure, the filament hole defining a second axis; as best seen in FIG.10 extending substantially perpendicular to the first axis; with the second axis being aligned with a bone screw (79) extending

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through the screw hole; the structure having a top surface and bottom surface; as best seen in FIG.9, the bottom surface being adapted to engage a top surface of a bone plate.

With respect to claims 3-7,9,13-19,23,31-34 Cole et al disclose all the limitations as set forth in column 14, lines 2-10; and, a best seen in FIGS: 9-10.

With respect to claims 24-28,35,36, 37, the method steps, as set forth would have been inherently carried out in the operation of the device, as set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10,11,20,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al. (6,068,648).

With respect to claims 10,11,20,21, it is noted that Cole et al. did not teach of a trapezoidal cross-section and a second upwardly projecting extension; as claimed by applicant. However, as to the trapezoidal cross-section, it is one of many geometric configurations one of ordinary skill in the art would have found obvious for the purpose of providing a shape to the washer. As to a second upwardly projecting extension, it would have been obvious to one having ordinary

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skill in the art at the time the invention was made to duplicate the first projecting extension, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Claims 8,18,38-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Cole et al.* (6,068,648) in view of *Schlapfer et al.* (5,993,449).

With respect to the above claims, it is noted that *Cole et al* did not teach all the limitations as set forth. However, in a similar art *Schlapfer et al.* evidences the use of a device having a set of screw hole and screw and an upwardly extension being displaced laterally; as claimed by applicant. However, in a similar art, *Schlapfer et al* evidences the use of a device having a set of screw hole and screw to accommodate an secure a cable and an upwardly extension being displaced laterally to facilitate the insertion of the cable.

Therefore, given the teaching of *Schlapfer et al.*, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the design of the device of *Schlapfer et al* in the device of *Cole et al* to accommodate and secure a cable and to facilitated the insertion of the cable.

Claims 22,29,30,45 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Cole et al.* (6,068,648) in view of *Corsi et al.* (5,190,545).

With respect to the above claims, it is noted that *Cole et al* did not teach of a bone plate and a recess formed in the bone plate; as claimed by applicant. However, in a similar art, *Corsi et al* evidences the use of a bone plate with a

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recess in the bone plate to retain a washer for accommodating a cable and position it relative to the aperture in the bone.

Therefore, given the teaching of Corsi et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a plate and recess in the device of Cole et al. to retain a washer for accommodating a cable and position it relative to the aperture in the bone.

Response to Amendment

Applicant's arguments with respect to claims 1-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6,544,267	04-2003	Cole et al.
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene
October 17, 2003



PEDRO PHILOGENE
PRIMARY EXAMINER